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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,836	10/04/1999	CARL GUSTAV FIGDOR	VEOC.002.00U	8137

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LAW OFFICE OF TRASK, BRITT, AND ROSSA
ATTN: MR. A.C. TURNER
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/214,836

Applicant(s)

FIGDOR ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,11,14,15,19-22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,11,14,15,19,21,22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2,4,11,14,15,19-22,24 and 25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed February 13, 2002 in Paper No. 14 is acknowledged and has been entered. Claims 1, 6, 7, 23, and 26-29 have been canceled. Claims 2, 4, 11, 14, 15, 21, and 22 have been amended.

2. Claims 2, 4, 11, 14, 15, 19-22, 24, and 25 are pending in the application. Claim 20 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. Claims 2, 4, 11, 14, 15, 19, 21, 22, 24, and 25 are currently under prosecution.

Election/Restrictions

4. Applicants have remarked in Paper No. 14 that claim 20 is drawn to the same subject matter as claim 1 and therefore should be viewed as part of the elected invention. In reply to Applicants' remark, it is noted that claim 20 is drawn to the same subject matter as claim 3, which is restricted from the subject matter of the elected invention in the Office Action mailed November 21, 2001 (Paper No. 8). Furthermore, contrary to Applicants remark, the subject matter of claim 1 and claim 20 are not the same. Accordingly, claim 20 has been withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a non-elected invention.

Priority

5. In the previous Office Action mailed September 11, 2001 (Paper No. 11), Applicants were advised that to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), Applicants should also file a claim for such priority as required by 35 U.S.C. 119(b). In reply to the Office Action Applicants have submitted an unsigned copy of a declaration, which claims the benefit of the filing date of EP 96201945.1.

Accordingly, Applicants intent to meet the requirements 35 U.S.C. § 119(a)-(d) is acknowledged; however, the new declaration remains unexecuted.

6. Furthermore, in reply to the previous Office Action, Applicants have amended the specification to properly claim benefit of the earlier filing date of PCT/EP97/03712 according to the requirement set forth under 37 CFR § 1.78. Accordingly, acknowledgment of the claims for domestic priority under 35 USC §§ 120 and/or 121 is made.

Claim Objections

7. In the previous Office Action an objection to claims 6 and 7 was made. In the amendment filed February 13, 2002, Applicants canceled claims 6 and 7, thus rendering the grounds of objection moot. Accordingly, the objection to claims 6 and 7 is withdrawn.

Applicants have noted in their remarks that claims 6 and 7 had been included in Group 1, which Applicants elected in Paper No. 10. In reply to Applicants remark, claims 6 and 7 had been included in Group 1 only insofar as the claims had been drawn to a vaccine comprising a peptide or an epitope thereof. Otherwise in the Office Action mailed November 21, 2001 (Paper No. 8), claims 6 and 7 insofar as the claims had been drawn to a vaccine comprising a nucleic acid molecule had been restricted to Group 3.

8. In the previous Office Action claim 19 had been objected to because there did not appear to be sufficient antecedent basis in the specification for the claim language recited in the claim. In reply to the Office Action Applicants have amended the specification to recite an antecedent basis for the language of claim 19, thereby obviating the grounds of objection. Accordingly, the objection to claim 19 is withdrawn.

Grounds of Claim Rejections Withdrawn

9. In the previous Office Action, claims 1, 2, 4, 6, 7, 11, 14, 15, 19, and 21-29 were rejected under 35 U.S.C. 112, second paragraph. In reply to the Office Action,

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Applicants have canceled claims 1, 6, and 28, thereby partially rendering the grounds of rejection of claims 2, 4, 14, 15, 19, 21, 22, 24, and 25 moot. Furthermore, Applicants have amended claims 11 and 21 to obviate the remaining grounds of rejection. Accordingly, the rejection of claims 2, 4, 11, 14, 15, 19, 21, 22, 24, and 25 under 35 USC § 112, second paragraph for the reasons stated in the previous Office Action is withdrawn.

Claim Rejections Maintained and Response to Applicants' Remarks

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 21, 22, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons stated in the previous Office Action mailed September 11, 2001 (Paper No. 11).

Claims 21, 22, 24, and 25 are drawn to a vaccine comprising the peptide of claims 2 or 4, which according to the specification can be used to treat a patient diagnosed with melanoma. However, the teachings of the specification cannot be extrapolated to the enablement of the claimed invention, because the amount of guidance, direction, and exemplification disclosed in the specification is not reasonably commensurate with the breadth of the claims. Accordingly in view of the state of the art, both currently and at the time the application was filed, and further view of the high level of unpredictability in the art, in the absence of working exemplification that is reasonably commensurate with the claims, the skilled artisan could not make and/or use the claimed invention with a reasonable expectation of success without need to perform undue experimentation.

Applicants have traversed these grounds of rejection under 35 USC § 112, first paragraph arguing:

(a) The limitation of treating a patient diagnosed with melanoma was found in the specification.

(b) The peptide of claim 2, which consists of the amino acid sequence of SEQ ID NO: 9 but for the replacement of threonine at position 2 for valine, elicited a greater immune response than SEQ ID NO: 9.

(c) The Office is not taking into account what is actually being claimed and is instead focusing on a potential use of the claimed invention. However, the claims do not recite a limitation requiring the invention to be used to treat a patient diagnosed with melanoma.

(d) One skilled in the art, given only benefit of Applicants' disclosure, could make and use the claimed peptides and vaccines without need to perform undue experimentation.

(e) Requiring a working example in which animals or patients are successfully treated using the claimed invention is improper and discriminatory.

In reply to Applicants' arguments, the claims are drawn to a vaccine. According to On-line Medical Dictionary © 1998-2002, "vaccine" is a pharmacological term, which is defined as "[a] suspension of attenuated or killed microorganisms (bacteria, viruses or rickettsiae), administered for the prevention, amelioration or treatment of infectious diseases". However, in this instance, the vaccine comprises a peptide, rather than a suspension of attenuated or killed microorganisms, and is administered to prevent, ameliorate, or treat cancer, rather than an infectious disease. Given light of Applicants' disclosure, it is apparent that Applicants contemplate using their invention to prophylactically and therapeutically treat patients diagnosed with melanoma. In fact, otherwise, it appears that the invention has no other asserted utility. Moreover, a tumor vaccine has no other utility in the art; it is administered to patients to elicit an immune response against a tumor antigen and thereby prevent the incidence or reoccurrence of a tumor expressing the tumor antigen in the patients, or to eliminate or reduce the patients' tumor burden.

The claims must be examined in light of the specification. Since the specification teaches that the claimed invention can be used to treat patients that have been diagnosed with melanoma, to meet the enablement requirements of 35 USC § 112, first paragraph, the disclosure must be sufficient to enable the skilled artisan to make and use the claimed invention with a reasonable expectation of success without need to perform undue experimentation. For the reasons stated in the previous Office Action, one skilled in the art could not make and use the claimed invention with a reasonable expectation of success without need to perform undue experimentation. Therefore, the disclosure fails to meet the enablement requirement of 35 USC § 112, first paragraph.

Applicants state that Figures 4 and 5 demonstrate that the peptide of claim 2, which consists of the amino acid sequence of SEQ ID NO: 9 but for the replacement of threonine at position 2 for valine, elicits a greater immune response than the peptide of SEQ ID NO: 9. However, contrary to Applicants' statement, upon examination of Figure 4, it appears that the analogue in which the threonine residue at position 2 is replaced by a valine residue is no more immunogenic than the peptide of SEQ ID NO: 9. The very slight difference between the amounts of lysis observed in the presence of the analogue and the peptide of SEQ ID NO: 9 does not appear to be statistically significant.

Applicants contend that one skilled in the art, given only benefit of Applicants' disclosure, could make and use the claimed peptides and vaccines without need to perform undue experimentation. Furthermore, Applicants assert that requiring a working example in which animals or patients are successfully treated using the claimed invention is improper and discriminatory. Although Applicants are not required to disclose working exemplification of the claimed invention, Applicants are required to provide a sufficient amount of guidance, direction, and exemplification to enable the skilled artisan to make and use the claimed invention with a reasonable expectation of success without need to perform undue experimentation. For the reasons stated in the previous Office Action, given only the benefit of Applicants' disclosure, the skilled artisan could not make and use the claimed invention with a reasonable expectation of success without need to perform undue experimentation. Therefore, the grounds of

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rejection are not improper, and there is no basis for Applicants' assertion that the grounds of rejection are discriminatory. The Office has not required Applicants to seek and acquire the approval of the Food and Drug Administration. Nevertheless, Applicants are required to fulfill the requirements of 35 USC § 112, first paragraph.

Applicants' arguments have been carefully considered but not found persuasive. Therefore, the rejection of claims 21, 22, 24, and 25 under 35 U.S.C. 112, first paragraph for the reasons stated in the previous Office Action are maintained.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 2, 11, 22, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,844,075-A ('075) for the reasons stated in the previous Office Action mailed September 11, 2001 (Paper No. 11).

As stated in the previous Office Action, '075 teaches a vaccine comprising a pharmaceutically acceptable carrier and a peptide comprising at least part of the amino acid sequence of SEQ ID NO: 9 wherein an original amino acid at position 2 or 8 is substituted with a replacement amino acid and wherein said peptide is immunogenic with lymphocytes directed against metastatic melanomas, wherein said original amino acid at position 2, threonine, is substituted by a replacement amino acid selected from the group consisting of isoleucine, leucine, and valine. '075 also teaches a method for isolating melanoma antigen reactive tumor infiltrating lymphocytes, wherein said method comprises reacting said lymphocytes with the peptide of claim 2. '075 also teaches that the peptides of can be conjugated to molecules that can be detected. '075 also teaches that the conjugated peptides can be packaged in a kit. See abstract; column 3, lines 41-51; column 12, lines 8-53; column 16, lines 9-30; column 17, lines 22-35; columns

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28-29, 41-43, and 60; columns 56 and 57, Table 15; and columns 58 and 59, Table 18. Thus, according to the previous Office Action, all the limitations of the claims are met by the teachings of '075.

Applicants traverse these grounds of rejection under 35 USC § 102(b) stating that '075 does not teach a peptide having the amino acid sequence set forth in SEQ ID NO: 9 but for the replacement of the threonine at position 2 by valine. Therefore, Applicants contend that '075 does not anticipate the claimed invention.

In reply to Applicants' arguments, '075 teaches (column 14, lines 45-56; emphasis added):

By way of example, the HLA-A2 allele binds peptides of nine or ten amino acids. Examples of positions within the peptide that may be altered to enhance binding include, but are not limited to, the first position, the second position, the third position and the last position of the peptide. Any amino acid may be used to substitute or replace these positions within the immunogenic peptide sequence. For enhanced binding to HLA-A2 the amino acid at the second position of the peptide is preferably a hydrophobic aliphatic amino acid. **Examples of amino acids that may be used at the second position include**, but are not limited to, leucine, methionine, alanine, isoleucine, **valine**, threonine or glycine.

Thus, contrary to Applicants' contention, the teachings of '075 anticipate the claimed invention because '075 teaches that the second position of the peptide can be replaced with a valine. Furthermore, it is noted that the claims only require the peptide to comprise part of the amino acid sequence set forth in SEQ ID NO: 9; therefore, it is not necessary that the peptide of the prior art comprise the portion of SEQ ID NO: 9 wherein a replacement is required to be made.

Applicants' arguments have been carefully considered but have not been found persuasive. Therefore, the rejection of claims 2, 11, 14, 22, and 25 under 35 U.S.C. 102(e) for the reasons stated in the previous Office Action is maintained.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

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patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 2, 11, 14, 19, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,844,075-A ('075) for the reasons stated in the previous Office Action mailed September 11, 2001 (Paper No. 11).

As stated in the previous Office Action, '075 teaches a peptide according to claim 2. However, '075 does not explicitly teach a conjugate of a peptide and a radionuclide. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to conjugate the peptide of '075 to a radionuclide, because the presence of the conjugated peptide would be detectable. Furthermore, as stated in the previous Office Action, one of ordinary skill in the art at the time the invention was made would have been motivated to make and use a conjugate the peptide of '075 and a radionuclide, because the conjugate could facilitate detection of CTL that bind the peptide and it would be useful to separate CTL that bind the peptide from CTL that do not bind the peptide since such a separation would reduce non-specific background cytotoxicity resulting from spurious non-peptide-specific effector activity.

Applicants have traversed the grounds of the rejection of the claims under 35 USC § 103(a), arguing that the mere fact that the reference can be modified does not render the invention obvious unless the reference also suggests the desirability of the modification. Therefore, Applicants have asserted that the claimed invention would not have been obvious over the teachings of '075.

Contrary to Applicants' assertion, since '075 teaches a method for isolating melanoma antigen reactive tumor infiltrating lymphocytes, wherein said method comprises reacting said lymphocytes with the peptide of claim 2, and also teaches that the peptides of can be conjugated to molecules that can be detected, one of ordinary skill in the art would have been given sufficient motivation to use a radionuclide as a detectable label. Radionuclides were the most conventionally used detectable labels.

Applicants' arguments have been carefully considered but have not been found persuasive. Therefore, the rejection of claims 2, 11, 14, 22, and 25 under 35 USC §

103(a) as being unpatentable over US Patent No. 5,844,075-A ('075) for the reasons stated in the previous Office Action is maintained.

New Grounds of Objections

Objection to the Specification

16. The amendment filed February 13, 2002 in Paper No. 14 is objected to under 35 USC § 132 because it introduces new matter into the disclosure. 35 USC § 132 states no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is the phrase "or other diagnostic marker known in the field".

Applicants are required to cancel the new matter in the reply to this Office Action.

Objection to the Claims

17. Claims 21, 22, 24, and 25 are objected to because claims 21 and 22 are drawn in the alternative to the subject matter of a non-elected invention. Appropriate correction is required.

New Grounds of Claim Rejections

Claim Rejections – 35 USC § 112

18. Claims 2, 4, 14, 15, 19, 21, 22, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2 and 4 recite the limitation "wherein said peptide is capable of inducing an increased binding affinity towards lymphocytes". However, there does not appear to be adequate antecedent basis in the specification for recitation of this "capable of inducing an increased binding affinity towards lymphocytes". Accordingly, amending claims 2 and 4 to recite the limitation appears to introduce new matter, thereby violating the written description requirement of 35 USC § 112, first paragraph. This matter might

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be resolved if Applicants were to point to specific disclosures in the specification that are believed to provide proper support for recitation of the limitation in the claims. Otherwise, Applicants should amend the claims to recite the explicit language of the specification.

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 2, 4, 11, 14, 15, 21, 22, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, 11, 14, 15, 21, 22, 24, and 25 are vague and indefinite because claims 2, 4, and 11 recite the limitation "wherein said peptide is capable of inducing an increased binding affinity towards lymphocytes". Recitation of the limitation renders the claims vague and indefinite for the following reasons:

(a) Recitation of "capable of" renders the claims vague and indefinite because it cannot be ascertained whether the claims require the peptide to be able to induce an increased binding affinity or merely to have the potential of doing so. Furthermore, if the latter, it is unclear under which conditions the claims require the peptide to induce an increased binding affinity.

(b) Recitation of "increased" renders the claims vague and indefinite because the term "increased" is a relative term, which is not defined in the claim. Because the specification does not provide a standard for ascertaining the requisite degree of increase, it is unclear to what extent the claims require the peptide to increase the binding affinity.

(c) Recitation of the limitation renders the claims vague and indefinite because the specification does not teach that the peptide can "induce" an increased binding affinity, but moreover it cannot be determined to what subject matter the claims require the peptide to induce to have a greater binding affinity towards lymphocytes. How is the

peptide required to induce an increase in the binding affinity of this undisclosed subject matter?

For each of the above reasons, the claims are vague and indefinite, failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Conclusion

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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slr

May 3, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600